

Remarks

Claims 11-26 and 31-34 were pending in the subject application. By this Amendment, claims 11 and 31 have been amended. Accordingly, claims 11-34 are currently before the Examiner. Favorable consideration and entry of the amendments presented herein are respectfully requested.

The amendments to the claims have been done to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments to the claims should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Support for these amendments can be found throughout the subject specification including, for example, at page 5, lines 3-5 and in Figure 1. The undersigned avers that no new matter is introduced by this amendment. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The applicant wishes to thank Examiner Mathew and Supervisory Patent Examiner Yu for the courtesy extended to the undersigned as well as to Dr. Boyd and Mr. Perry during the personal Examiner Interview conducted on December 2, 2004. This response and the amendments set forth herein are submitted in accordance with the substance of that interview and constitute a summary thereof. Specifically, in order to expedite prosecution, the applicant has focused the claims at this time on the applicant's unique device for healing wounds on a leg, wherein the device includes a fluid absorbent material at the closed end of the device. Unlike anything in the prior art, the device of the subject invention absorbs wound exudate and advantageously promotes wound healing.

The device of the subject invention advantageously promotes the healing of wounds by providing a warm and moist environment with adequate oxygenation and prevention of gross contamination, while capturing wound exudates with a fluid absorbent material. The subject invention allows natural exudates from the wound to carry material away from the affected site and be deposited at the fluid absorbent material, thus encouraging wound healing. Further, by allowing exudates to drain away from the wound, the present invention encourages active growth factors and reduces the level of proteinases thereby supporting the wound healing process, while preventing excoriation of unaffected skin.

Claims 11-13, 22, 25-26, and 31-33 have been rejected under 35 U.S.C. §103(a) as obvious over the Botha *et al.* reference (U.S. Patent No. 5,395,302) in view of Orange *et al.* (U.S. Patent No. 5,817,038). The applicant respectfully traverses this ground of rejection because these references, either alone, or in combination, do not teach or suggest the claimed device.

As acknowledged in the instant Office Action, the Botha *et al.* reference does not teach the applicant's unique device. The device of the Botha *et al.* reference provides a waterproof bag that lacks any fluid absorbent materials. The Botha *et al.* bag keeps water from coming into the device from the outside (see col. 1, lines 11-13).

Botha *et al.* define the problem to be solved by their invention as follows:

It often happens that a person who has an injured limb is faced with the problem of keeping the limb dry when bathing or washing parts of the body adjacent to the limb in question. (Column 1, lines 7-10).

Both *et al.* do not disclose or suggest the use of a fluid-absorbent material. In fact they state:

Experimentation indicates that the seal formed against the skin by the sealing strip 22 is sufficient to prevent ingress into the sleeve of water during normal bathing or washing procedures. Once the wearer has finished bathing, he forcibly separates the male and female components of the VELCRO hook-and-loop fastener, unwinds the strap 32 and withdraws his forearm and hand from the limb sheath 10 which can be stored for re-use when required again. (Column 3, lines 29-38).

As emphasized by Dr. Boyd during the recent personal interview, the device of the current invention is not concerned with keeping water out of the enclosure. Rather, the device promotes an advantageous wound-healing environment by absorbing large amounts of wound exudates produced inside the enclosure.

The Orange *et al.* reference describes another device designed to keep water out of a wound enclosure. The Orange *et al.* device is a waterproof sleeve that has two closeable cuffs, where fluid absorbent materials are provided at the cuffs to prevent entry of water into the sleeve (see col. 2, lines 32-36). One skilled in the art would not have been motivated to modify the Botha *et al.* bag, in

view of the Orange *et al.* sleeve, to incorporate a fluid absorbent material at a closed end of the device in order to capture wound exudates. In fact, both references' emphasis on preventing entry of water into the enclosure and maintenance of a dry environment within the enclosure essentially teaches away from the device of the current invention.

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, it is only the applicant's disclosure that provides such a teaching, and the applicants' disclosure cannot be used to reconstruct the prior art for a rejection under §103. This was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Srock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The mere fact that the purported prior art could have been modified or applied in a manner to yield applicant's invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, “[b]oth the suggestion and the expectation of success must be founded in the prior art. . . .” *In re Dow Chemical Co., supra* at 1531. (emphasis added)

The applicant respectfully submits that any suggestion to make a device for use on a wound on a leg, wherein the device includes a fluid absorbent material at the closed end of the device, could only be arrived at through hindsight reconstruction of the art, which is improper. Rather, a person skilled in the art at the time of the subject invention, having knowledge of the Botha *et al.* and Orange *et al.* references would have no reason to create a device that has a fluid absorbent material inside the enclosure, away from the opening. Accordingly, reconsideration and withdrawal of this rejection under 35 USC §103(a) is respectfully requested.

Claims 15-18, 21 and 23 have been rejected under 35 U.S.C. §103(a) as being obvious over the Botha *et al.* reference in view of the Orange *et al.* reference and further in view of the Liman reference (U.S. Patent No. 3,741,203). To the extent that this rejection might be applied to the claims now presented for examination, the applicant respectfully traverses this ground for rejection because these references, either alone or in combination, do not teach or suggest the subject device or the claimed method.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation to combine the teachings of the cited references to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). The applicant respectfully submits that the cited references are devoid of any teaching, suggestion, or motivation to combine them to arrive at the subject invention.

The shortcomings of the Botha *et al.* and Orange *et al.* references have been discussed above. As with the Botha *et al.* bag and Orange *et al.* sleeve, the Liman covering is intended to prevent water or other contaminants from entering an enclosure and contacting the limb within the covering. To ensure that no water or contaminant enters the covering, an annular foam is secured adjacent the open mouth of the Liman covering (see, for example, col. 4, lines 44-61; Figure 2). Liman neither discloses nor suggests a device and method utilizing an absorbent layer at the closed end. In contrast to the Liman device, which merely provides a protective cover against entry of water or contaminants, the present invention provides devices and methods for the treatment of a wound while preventing excoriation of unaffected skin, by absorbing fluid that is produced by the wound.

The applicant respectfully submits that a person skilled in the art at the time of the subject invention, even having knowledge of the Botha *et al.*, Orange *et al.*, and Liman references would have had no motivation to provide a fluid-absorbent material at the closed end of a device for covering a limb. Accordingly, reconsideration and withdrawal of this rejection under 35 USC §103(a) is respectfully requested.

Claims 14 and 34 have been rejected under 35 U.S.C. §103(a) as obvious over Botha *et al.* in view of Orange *et al.* and further in view of Shuler (U.S. Patent No. 2,690,415). The applicant

respectfully traverses this ground of rejection because the Botha *et al.* and the Orange *et al.* references, even in view of the Schuler reference do not teach or suggest the claimed device.

In addressing this rejection, the applicant hereby incorporates and resubmits his remarks concerning the Botha *et al.* and Orange *et al.* references as set forth in the preceding paragraphs. As described above, neither the Botha *et al.* nor the Orange *et al.* reference disclose or suggest a device wherein the device has a fluid-absorbent material positioned at the closed end of the device. The Shuler reference does not teach, either expressly or impliedly, a device that provides a fluid absorbent material to capture wound exudates and prevent excoriation. Further, the Shuler reference fails to disclose a device that provides a warm and moist environment to promote the healing of a wound. One skilled in the art, having the Orange *et al.*, and Shuler references, would not be motivated to modify the Botha *et al.* bag to include a fluid absorbent material positioned at the closed end. Accordingly, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

Claims 19-20 have been rejected under 35 U.S.C. §103(a) as obvious over Botha *et al.* in view of Orange *et al.* and Shuler, and further in view of Liman. The applicant hereby incorporates and resubmits his remarks concerning the Botha *et al.*, Orange *et al.*, Shuler, and Liman references as set forth in the preceding paragraphs to address this rejection. As noted above, the Botha *et al.*, Orange *et al.*, Shuler, and Liman references all fail to describe a device for placement over a leg that has a fluid absorbent material positioned at a closed end. Accordingly, reconsideration and withdrawal of this rejection under 35 USC §103(a) is respectfully requested.

Claim 24 has been rejected under 35 U.S.C. §103(a) as obvious over Botha *et al.* in view of Orange *et al.* and further in view of Augustine (U.S. Patent No. 5,947,914). The applicant respectfully traverses this grounds of rejection because the neither the Botha *et al.*, the Orange *et al.*, nor the Augustine reference disclose or suggest a device that promotes a warm and moist environment for a wound while ensuring the unaffected portion of a limb remains dry to prevent excoriation.

In addressing this rejection, the applicant hereby incorporates and resubmits his remarks concerning the Botha *et al.* and Orange *et al.* references as set forth in the preceding paragraphs. The

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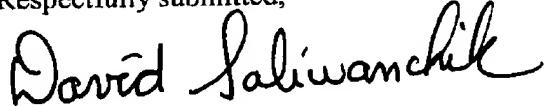
Augustine reference does not cure the aforementioned shortcomings of the primary reference. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a) is respectfully requested.

In view of the foregoing remarks and the amendment above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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